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INFERTILITY

Medical and Social Choices

Summary

CONGRESS OF THE UNITED STATES OFFICE OF TECHNOLOGY ASSESSMENT

WASHINGTON, DC 20510-8025

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Foreword

From the 1978 birth of Louise Brown, conceived through in vitro fertilization, through last year's *Baby M* case on surrogate motherhood, much attention has focused on new options available to help infertile couples form a family. Still, most infertile couples who seek help are treated with conventional drug therapy or surgery. In this assessment, OTA analyzes the scientific, economic, legal, and ethical considerations involved in both conventional and novel reproductive technologies.

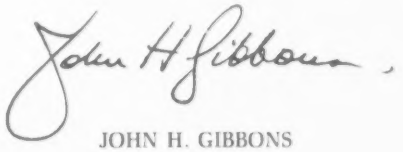
The report was requested by the Senate Committee on Veterans' Affairs and the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations. It illustrates a range of options for congressional action in nine principal areas of public policy related to infertility:

- collecting data on reproductive health;
- preventing infertility;
- information to inform and protect consumers;
- providing access to infertility services;
- reproductive health of veterans;
- transfer of human eggs, sperm, and embryos;
- recordkeeping;
- surrogate motherhood; and
- reproductive research.

In gathering information for this study, OTA staff made site visits to 10 in vitro fertilization clinics, three sperm banks, two Veterans' Administration hospitals, and one large private medical practice that provides infertility treatment not involving novel reproductive technologies. The site visits were made in California, Louisiana, Maryland, New York, Texas, Virginia, Washington, and Australia.

OTA was assisted in preparing this study by a panel of advisors and reviewers selected for their expertise and diverse points of view on the issues covered in the assessment. Advisory panelists and reviewers were drawn from medicine, academia, the pharmaceutical industry, professional societies, religious groups, family planning groups, Federal agencies, and infertile couples. Written comments were received from 72 reviewers on the penultimate draft of the assessment. Comments on an appendix describing events in 43 foreign nations were received from an additional 60 reviewers.

OTA gratefully acknowledges the contribution of each of these individuals. As with all OTA reports, responsibility for the content is OTA's alone.



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NOTE: OTA appreciates and is grateful for the valuable assistance and thoughtful critiques provided by the advisory panel members. The panel does not, however, necessarily approve, disapprove, or endorse this report. OTA assumes full responsibility for the report and the accuracy of its contents.

Infertility: Medical and Social Choices

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Summary, Policy Issues, and Options for Congressional Action

This assessment is about the estimated 2 million to 3 million American couples who want to have a baby, but who either need medical help to do so or will remain frustrated in their desire.

In response to requests from the Senate Committee on Veterans' Affairs and the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations, this assessment presents the scientific, legal, economic, and ethical issues surrounding infertility. Specifically, it assesses medically assisted conception, surgically assisted conception—including in vitro fertilization (IVF) and gamete intrafallopian transfer (GIFT)—artificial insemination, basic research supporting reproductive technologies, and surrogate motherhood.

It is important to note that infertility is not only a personal medical problem, but also in some ways a social construct. It is in part a manifestation of the American commitment to a complex, pluralistic society, in which childbearing is balanced, for example, with education or career goals. This study does not examine reasons, for example, why a couple may postpone forming a family. Instead, it is limited to technologies that help establish a pregnancy. Certain allied issues, such as management of pregnancy, prenatal diagnosis including embryo biopsy, termination of pregnancy, fetal research, child health, adoption, and alternate family arrangements involving child sharing, are also beyond the scope of this report.

HOW BIG A PROBLEM IS INFERTILITY?

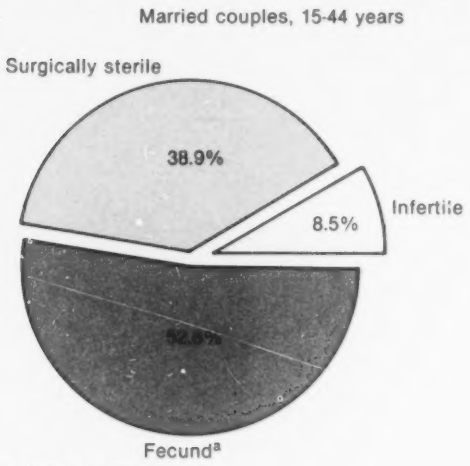
Infertility, generally defined as the inability of a couple to conceive after 12 months of intercourse without contraception, affects an estimated 2.4 million married couples (data from 1982) and an unknown number of would-be parents among unmarried couples and singles. It is an important personal and societal problem:

- Diagnosis and treatment are costly, time-consuming, intrusive, and carry about an even chance of failure.
- Avenues for prevention of infertility are uncertain.
- The substantial number of involuntarily childless people hinders the development of families, long regarded as the backbone of American society.
- Sexual behavior for both partners experiencing the stress of infertility may change radically and induce marital strife.
- Involuntarily childless couples may have to contend with family disharmony in addition to their personal disappointment.
- Infertility is often an unexpected disappointment, affecting an individual's perception of self and place in the larger scheme of generations backward and forward in time.
- Infertility frustrates one of the most basic human desires—that is, to have children.

The sole reliable sources of demographic information about infertility in the United States are national surveys conducted by the National Center for Health Statistics (NCHS). The most recent was conducted in 1982; a new survey began in 1988, and data will be available in 1989. **In 1982, an estimated 8.5 percent of married couples with wives aged 15 to 44 were infertile**, 38.9 percent were surgically sterile, and 52.6 percent were fertile, or more precisely, fecund (see figure 1). It is important to note that surgical sterilization masks some couples who were infertile anyway. (If those who were surgically sterile are excluded from the population base, the 2.4 million couples account for 13.9 percent of the remaining 17.3 million couples.) **Infertility generally increases with age** (see figure 2).

The overall incidence of infertility remained relatively unchanged between 1965 and 1982 (see figure 3). **One age group, married couples**

Figure 1.—Infertility in the United States, 1982



[a]Potentially able to conceive.

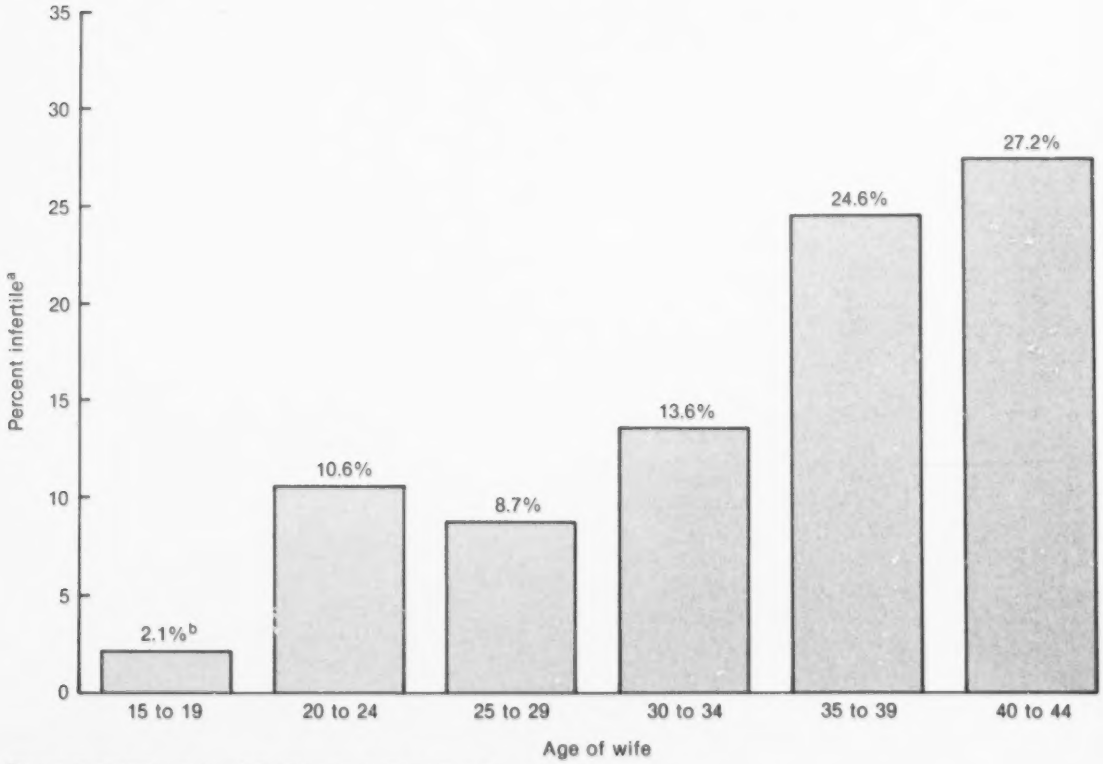
SOURCE: Office of Technology Assessment, 1988.

with wives age 20 to 24, exhibited an increase in infertility (from 3.6 percent infertile in 1965 to 10.6 percent infertile in 1982). This increase may be linked to the rate of gonorrhea in this age group—a rate that tripled between 1960 and 1977.

Childlessness, or primary infertility, has increased and affects about 1.0 million couples. Secondary infertility (in which couples have at least one biological child) has decreased and affects about 1.4 million couples. Surgical sterilization has increased dramatically (see figure 4). Certain couples are more likely than others to be infertile: The incidence among blacks, for example, is 1.5 times higher than among whites.

It is noteworthy that not all infertile couples seek treatment. An estimated 51 percent of couples with primary infertility and 22 percent with secondary infertility seek treatment.

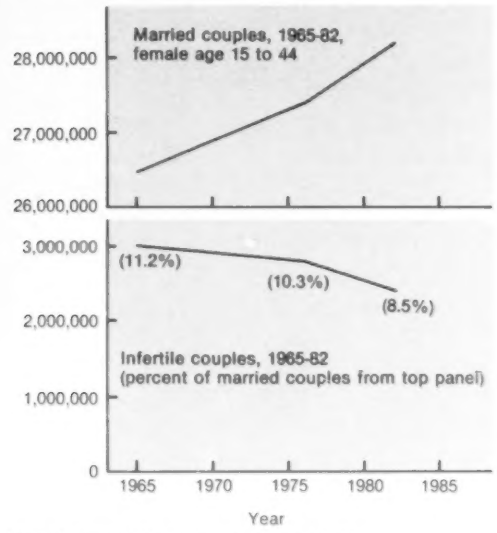
Figure 2.—Infertility and Age, 1982



[a]Percent of married couples, excluding those surgically sterilized, who are infertile.
[b]Likely an underestimate because married teenagers have not yet had time to discover that they are infertile.

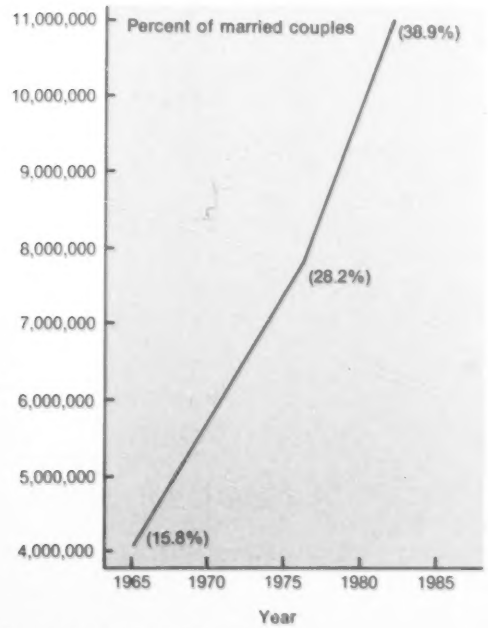
SOURCE: Adapted from W.D. Mosher, "Infertility: Why Business is Booming," *American Demographics* 9:42-43, 1987.

Figure 3.—Married Couples and Infertility, 1965-82



SOURCE: Office of Technology Assessment, 1988.

Figure 4.—Surgically Sterile Couples,[a] 1965-82

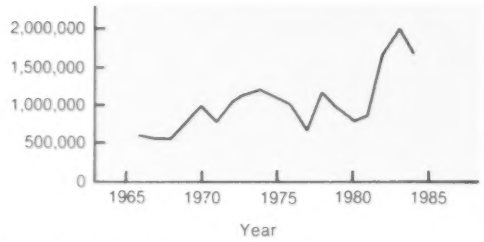


[a]One or both partners surgically sterilized.

SOURCE: Office of Technology Assessment, 1988.

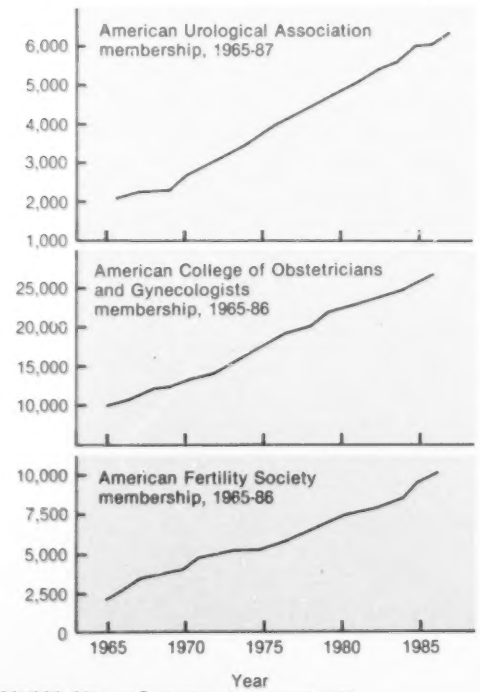
Although there has been no increase in either the number of infertile couples or the overall incidence of infertility in the population, the number of office visits to physicians for infertility services rose from about 600,000 in 1968 to about 1.6 million in 1984 (see figure 5). Concomitant increases occurred in the memberships of the American College of Obstetricians and Gynecologists, the American Fertility Society (AFS), and the American Urological Association, the three chief professional organizations for physicians who treat infertile patients (see figure 6).

Figure 5.—Physician Office Visits for Infertility, 1966-84



SOURCE: Office of Technology Assessment, 1988.

Figure 6.—Membership in Infertility Professional Organizations, 1965-86



SOURCE: Office of Technology Assessment, 1988.

WHAT FACTORS CONTRIBUTE TO INFERTILITY, AND CAN IT BE PREVENTED?

Three factors most often contribute to infertility among women: problems in ovulation, blocked or scarred fallopian tubes, and endometriosis (the presence in the lower abdomen of tissue from the uterine lining). Infections with sexually transmitted diseases (STDs), principally chlamydia and gonorrhea, are an important cause of damaged fallopian tubes. **Among men, most cases of infertility are a consequence of abnormal or too few sperm.** For as many as one in five infertile couples, a cause is never found.

Preventing infertility is difficult. Factors that contribute to abnormal or too few sperm, for example, are largely unknown. Other factors, like endometriosis, are not amenable to prevention. Nevertheless, prevention strategies are desirable, because they may help some couples avoid the considerable emotional and economic costs associated with infertility treatment, and they may preempt some infertility that would be wholly untreatable.

Infertility resulting from sexually transmitted diseases—an estimated 20 percent of the cases in the United States—is the most preventable. In these instances, prevention of infertility equals prevention (and rapid and effective treatment) of sexually transmitted diseases. The risk of infertility increases with the number of times a person has chlamydia or gonorrhea, the duration and severity of each infection, and any delay in instituting treatment.

Effective public health initiatives aimed at preventing STDs and infertility include efforts in the following areas:

- health education of patients and public health professionals;
- disease definition, including long-term sequelae of STDs;
- optimal treatment and improved clinical service;
- partner tracing and patient counseling; and
- research, including the social, psychological, and biologic aspects of STDs.

It is noteworthy that changes in sexual behavior, attitudes about discussing sex, and health education wrought by the epidemic of acquired immunodeficiency syndrome (AIDS) could have the salutary effect of preventing some infertility due to STDs.

The calculus of infertility includes the age of the prospective mother. The probability of infertility increases somewhat after age 30 and significantly more after age 35. Although no one social prescription fits all couples in all circumstances seeking to conceive, biology dictates that to maximize the chance of natural conception, a couple should maximize the number of months or years devoted to attempting it. A woman's reproductive lifespan is circumscribed, and whenever the decision to procreate is made, the chance of success generally depends on the number of months during which conception is attempted. **The probability of conception is reduced both by delaying childbearing and by condensing attempts into a relatively short time period.**

A promising area of research in prevention is the identification of behavioral, physiological, and environmental risk factors for infertility. One goal of such research is to help young adults take measures to preserve their future fertility. Table 1 summarizes preventive approaches for some known and hypothesized risk factors for infertility.

HOW IS INFERTILITY DIAGNOSED AND TREATED?

Infertile patients obtain care from an estimated 45,600 physicians: 20,600 obstetrician-gynecologists, 17,500 general or family practitioners, 6,100 urologists, and 1,400 surgeons. Sophisticated or innovative procedures for treating infertility cases are most likely to be available in urban areas and at university medical centers.

Fertility is the product of interaction between two people and so the infertile *patient* is in effect the infertile *couple*. Examination of the male is simplified by the fact that his reproductive organs and sperm are readily accessible. This accessibility is not, however, accompanied by better and more varied treatments for the male.

Table 1.—Prevention of Infertility

Factors predisposing individuals toward infertility and preventive steps available
Sexually transmitted diseases (STDs) and pelvic inflammatory disease (PID):
• Careful selection of possible sexual partners. Health education to discourage unprotected sexual encounters. Monogamy. Forthright inquiry and check of sexual partners for risks of STDs.
• Contraception by means of condoms. Use condoms routinely with new sex partner. Media campaign to encourage condom use.
• Periodic screening for STDs, if sexually active; STDs in both males and females are commonly asymptomatic.
• Changes in societal attitudes about STDs to lessen stigma of diagnostic examination for them.
• Recognize findings of STDs and seek medical care. Ensure that correct treatment is given for yourself and partner, with followup.
• Media campaign to encourage men and women with genital discharge to be checked for STDs.
• Rapid, adequate management of PID to reduce risk of sequelae.
Pelvic infections after birth, abortion, surgery, or invasive diagnostic testing:
• Ensure that optimally safe birth and surgical services are available.
• Use prophylactic antibiotics in high-risk situations to prevent infection.
Exercise, poor nutrition, and stress:
• Recognize that regular strenuous exercise (i.e., exceeding 60 minutes daily), rapid weight loss, low body fat, and stress may cause decreased fertility. Women are at higher risk than men.
Smoking, environmental toxins, and drugs:
• Smoking, as well as other substance abuse, reduces reproductive potential and should be avoided. Environmental exposures are inadequately studied, but appear more common in males. Semen analysis can be performed.
Endometriosis:
• If strong family history for endometriosis exists, consider oral contraception and possible specific endometriosis suppression. Oral contraceptives may suppress endometriosis even in those not at high risk.
• Early diagnosis and treatment in symptomatic women. Conservative surgical approaches.
Cryptorchidism and varicocele:
• Undescended, especially intra-abdominal, testes should be treated as promptly as possible. Benefits of surveillance and treatment of varicocele are controversial.
Chemotherapy and radiation:
• Risks of gonadal damage must be considered and, if appropriate, gamete collection or protection of the gonads should be performed.
Intercurrent illnesses:
• Many acute and chronic diseases cause anovulation or decreased spermatogenesis. Prevention of these effects is by treatment of the primary disease.
Inadequate knowledge of reproduction:
• Ensure that information on reproduction is available from parents, schools, clergy, and other sources.
Inadequate medical treatment:
• Couples with difficulty conceiving should educate themselves about fertility and seek specialized care before infertility is prolonged.
Lack of perspective about reproduction:
• Discuss family life with parents, peers, and professionals. Formulate life plan that allows adequate time for reproductive goals.

SOURCE: Office of Technology Assessment, 1988.

This is due, in part, to a continued lack of knowledge about male reproductive physiology. Female reproductive health can be estimated through a variety of indirect indicators (e.g., menstrual regularity, hormone levels, properties of cervical mucus) and direct methods (e.g., tissue biopsy, laparoscopy, ultrasound imaging). Even with sophisticated diagnostic technology, however, no fertility test can positively predict a woman's ability to conceive or maintain a pregnancy.

Among infertile couples seeking treatment, 85 to 90 percent are treated with conventional medical and surgical therapy. Medical treatment ranges from instructing the couple in the relatively simple methods of pinpointing ovulation to more complex treatments involving ovulation induction with powerful fertility drugs and artificial insemination. Surgical treatments also span a wide spectrum of complexity, ranging from ligation of testicular veins for eliminating varicocele to delicate microsurgical repair of reproductive tract structures in both men and women. Beyond being physically invasive, treatment is often emotionally taxing (see box A). Ovulation induction, surgery, and artificial insemination are the most widespread and successful approaches to overcoming infertility.

Two noncoital reproductive technologies—IVF and gamete intrafallopian transfer (GIFT)—offer hope to as many as 10 to 15 percent of the infertile couples who could not be successfully treated otherwise. These techniques are being practiced with increasing frequency, but proficiency varies widely. Some 70 to 80 medical teams in the United States have established a record of some success with IVF, and proficiency with GIFT is increasing. However, the remainder of the 169 IVF/GIFT programs in this country have had little or no success to date.

Counseling is an important and often underutilized component of infertility treatment.

Box A.—Infertility's Emotional Toll

Crazy Feelings Are Normal

You are sitting in the waiting room of your doctor's office. You have been trying to have a baby for 3 years and things are not happening the way you had planned. You have been on clomiphene for a year. Lately you cry at the drop of a hat—when you see a diaper commercial on television, see a pregnant woman at the grocery store, or get an invitation to a baby shower. The whole world seems to be having babies.

You always thought of yourself as competent, able to handle anything. Now you feel depressed every month when your period begins. You are beginning to think that having a baby is the only thing that will make your life worthwhile. You feel odd, different. *Everyone* can have a baby. *What's wrong with me?* You may start to wonder if you are getting a little crazy.

You find yourself experiencing feelings that you have never had before. Sometimes you are depressed when you never used to be, or you avoid situations that have anything to do with children. Over the last 6 months, the entries in your private diary include:

I must have done something wrong to deserve this.
I have to keep an important part of my life secret.
I have nobody I can talk to about this.
Sex on schedule takes all the joy out of making love.
Nobody understands how I feel, even my husband.
I'm angry all the time.
I feel as if everything in my life is on hold.
I'm always tired lately.
I've lost my self-confidence.
I feel like a failure in everything in my life.
I feel sad and alone.
I'm afraid my husband will give up on me.
We don't have fun anymore.
We don't fit in with our friends; they all seem to be into children.
My family can't support me like they used to, especially on special occasions when children are the center of attention.
If I could just stop trying so hard, maybe I could get pregnant.

Feelings of Helplessness and Responsibility

It is 2 p.m. You are sitting with your wife in the doctor's office, waiting to be told what to do next to get your wife pregnant. You gave a semen sample 2 days ago to some lab person. You are sure that humiliating experience was just the beginning of many more. You are wondering how bad your sperm are.

You think about your wife and how tense you feel when her period is due. It used to be, when you were first married and didn't yet want a baby, that you kept track of her period to make sure she wasn't pregnant. Now you are still counting days, but for the opposite reason. Times sure have changed; in the old days, you never gave infertility a thought.

You are afraid to ask how she is feeling and are ambivalent about listening to her talk about symptoms that sound like she is pregnant. You begin to get hopeful, yet worry about feeling let down when her period begins.

What if the doctor suggests a specialist, another semen sample, surgery on your testes? Don't they know how much you hate masturbating in the bathroom while they wait outside? You wonder if your wife will want to be with you if you can't give her a child. How will you explain to your family that you can't continue their name? What if your wife wants to use donor sperm? Can she possibly understand how defective and inadequate this makes you feel? The aloneness and disconnectedness is intense.

Your wife has always been your best friend, your confidant. How can you tell her how angry you feel that struggling to have this baby has created a distance between you? How can you tell her how sad you feel when she starts her period? How can you tell her how helpless you feel? How *responsible* you feel.

You stifle all that. She needs your support.

She asks if you hurt. You abbreviate your answer, thinking that it will be easier for her. You miss the old easy way you had with each other. Last week, you lashed out in a way that made it seem like you don't have any feelings about all that the two of you have been through. It only takes one sperm to impregnate an egg, so what's the big deal about the number and how well they move and what they look like? Most of all, you just hope the doctor will tell you what to do.

SOURCE: S.G. Mikesell and A. Hammond, Licensed Psychologists, Washington, DC, personal communications, Oct. 30 and Dec. 23, 1987.

Patients may derive psychological support from professional counseling at an infertility clinic, counselors in private practice, or community support groups. One nationwide support group for infertile people, Resolve, has 47 chapters nationwide.

As many as half the infertile couples seeking treatment will ultimately be unsuccessful, despite trying various avenues of treatment. Knowing when to stop treatment is an individual matter for each infertile couple. A decision often comes as couples ask themselves:

- Is further treatment worth the pain, expense, and disruption?
- Is adoption or childlessness becoming an acceptable option?
- Is treatment costing so much that other goals are sacrificed?
- If it is not yet time to stop, when will it be?

Conception is a matter of chance, and embryonic loss is a normal phenomenon in mammalian reproduction. Yet for those unable to have the child they want, infertility can be a lifelong legacy (see box B).

Box B.—The Lifelong Legacy of Infertility

Some infertile couples, confronted with the rather limited options by which they can enlarge their families, make the conscious choice to live their lives without children, perhaps deciding to channel their energies into work, recreation, creative endeavors, or philanthropic efforts. For some couples, this is fine. They feel their lives are full. For others, however, it is more difficult. They may worry about being the last of their genetic line. Some talk about being confronted prematurely with a sense of their own mortality.

For those who are troubled by their infertility, childlessness may disappear as a source of unhappiness during midlife, not to appear again until the late elderly years, and then as lack of an emotional and economic resource rather than as part of an identity crisis. Often the times we are most vulnerable to self-doubt are around life's milestones: retirement, menopause, or developments in the lives of family and friends, particularly those with children.

Some couples fear the isolation and loneliness of growing old alone, and from time to time they may wonder whether they will be able to handle the process of aging without an adult child or grandchildren to support them and offer company. In fact, as friends of the childless couple rejoice in births of grandchildren, the infertile couple may find that they feel social isolation emerging once again in their lives.

SOURCE: Office of Technology Assessment, 1988.

WHO ASSURES THE QUALITY OF INFERTILITY TREATMENT?

With treatments for infertility growing more sophisticated, it is increasingly important for patients to understand the realistic likelihood that these procedures will succeed (see box C), and to have reasonable assurance of quality care. Success rates among IVF clinics, for example, vary widely; nearly half have yet to achieve a live birth following IVF.

Professional societies—voluntary organizations of practitioners—such as the American Association of Tissue Banks, the American College of Obstetricians and Gynecologists, and the American Fertility Society have made efforts to regularize the practice of medically assisted conception. They have promulgated guidelines on gamete and participant screening, physician training, and clinic staffing. Compliance with such guidelines, however, is voluntary.

Couples seeking the most talked-about new reproductive technology, IVF, are often in a quandary over assessing practitioners' skills. Is IVF experimental or is it a proven medical therapy? In 1988, no blanket answer to that question is possible. Just as some physicians in IVF programs in the United States are proven practitioners of the art, others are as yet unproven.

In 1986, the American Fertility Society concluded that a procedure (e.g., IVF) done for the

Box C.—How IVF Success Rates Can Be Reported

In early 1988, 41 U.S. IVF clinics reported, as a group, their success rates for 1985 and 1986. These clinics represent about one-fourth of all IVF programs active in the United States and are generally the most successful. This first combined report of IVF clinics characterized the average 1986 IVF success rate as 16.9 percent (clinical pregnancy per embryo transfer cycle). ("Clinical pregnancy" denotes positive fetal heart documented by ultrasound.) This figure is one of several ways to calculate IVF success rates and may be misleadingly optimistic for some patients. It may also be inadequate to reflect success rates for procedures using frozen embryos obtained in earlier stimulation cycles.

It is important to note that regardless of how averages are expressed, they can be misleading for an individual patient. Patients who are older, who have a history of repeated miscarriages, or who have other special risk factors have smaller chances for success. Conversely, some candidates for IVF are much more likely than average to have a successful pregnancy.

Assuming an IVF candidate has passed a battery of tests determining her general appropriateness for the procedure, she's ready to start her first ovarian stimulation cycle. On average, 6 of 10 women are successful at stimulation and fertilization, leading to an embryo-transfer attempt. Following embryo transfer, the chance of becoming clinically pregnant is about **1 in 6 (16.9 percent)**, the figure highlighted in the report of the success rate of the 41 clinics. However, a woman still faces the risk—about a 1-in-3 chance—that her pregnancy is ectopic, or that it will end in a miscarriage or stillbirth. Therefore, her chance of walking out with a baby after one embryo transfer cycle is about **1 in 9 (10.7 percent)**. Calculated per stimulation cycle, a woman's chance of taking home a baby is about **1 in 16 (6.3 percent)**. She also has a 1 in 1,000 chance of winding up in the hospital due to hyperstimulation from the drugs.

On average, each patient at the 41 IVF clinics undertook 1.6 stimulation cycles, so the 1 in 16 chance of taking home a baby following one stimulation cycle can also be quoted as an overall **1 in 10 (10 percent) chance** of taking home a baby after undertaking an average course of IVF treatment.

Every couple is unique, and the chances of success may vary from the averages quoted here or by an IVF clinic. A particular patient's or clinic's past success with stimulation, egg retrieval, and fertilization may make one or another type of reported success rate more useful. Couples undertaking medically assisted conception should keep in mind that miscarriage rates are high for all pregnancies, IVF-induced or not, and that they may have to undergo many attempts before a successful pregnancy is achieved. With IVF, the odds per stimulation cycle, and even per embryo transfer, of taking home a baby are low.

SOURCE: Office of Technology Assessment, 1988, based on Medical Research International and the American Fertility Society Special Interest Group, "In Vitro Fertilization/Embryo Transfer in the United States: 1985 and 1986 Results From the National IVF/ET Registry," *Fertility and Sterility* 49:212-215, 1988.

first time by a practitioner or for the first time at a particular facility should be viewed as experimental, implying that after some number of attempts, the procedure is no longer experimental. AFS also stated that charges should be reduced until a clinic has established itself with a reasonable success rate, implying that a reasonable success rate characterizes the clinic as no longer providing experimental treatment. These lines of reasoning leave unclear whether it is the number of times IVF has been used or the success with which it is used that determines its experimental status.

Regulation of noncoital reproductive techniques has been primarily a matter for individual States, despite avenues of Federal authority. Regulation of quality control and of monitoring, safety, recordkeeping, inspection and licensing, obligations of mothers and fathers, and requirements for sperm donor screening are well within the traditional bounds of State responsibility related to medical practice and matters of family law. Federal activity in assisted reproduction has consisted largely of supporting national commissions to study scientific, legal, and ethical issues.

HOW MUCH DOES INFERTILITY COST?

The dollar value of the personal, familial, and societal losses caused by infertility is inestimable. Americans spent, however, about $1 billion on medical care in 1987 to combat infertility. Approximately 7 percent of the total was spent on IVF. Some 14,000 attempts at IVF were performed in 1987. In other words, IVF was undertaken by less than 1 percent of the estimated number of infertile couples in the United States who sought treatment.

Costs to individual couples receiving care for infertility vary dramatically, depending on the severity of their problem and their perseverance in seeking treatment. A complete diagnostic workup typically costs $2,500 to $3,000, although most couples do not require such an extensive workup. Medical treatment may cost an additional $2,000 to $8,000; in the extreme, medical treatment may cost more than $22,000. Further, because conception is a precisely timed biological event, infertility diagnosis and treatment often involve the costs of time away from work and may involve travel and hotel costs.

Many private health insurers do not cover infertility per se or provide only limited coverage, yet in practice a substantial portion of infertility expenditures are reportedly reimbursed. Some individual procedures are covered, particularly if they are not identified as part of an overall treatment for infertility. In other instances, some physicians find disingenuous ways to invoice for infertility services, so as to obtain reimbursement from insurers for their patients. Treatment related to IVF is specifically excluded from coverage by the majority of health plans, but substantial reimbursement occurs for the various components of IVF treatment (e.g., hormonal stimulation). Subterfuge by some physicians in order to obtain reimbursement for their patients from insurers is reported to include invoicing for egg retrieval for IVF under the guise of "aspirating a trapped oocyte."

IVF patients undertake an estimated two IVF cycles on average, with most of them ceasing treatment after that for financial reasons, prior to achieving a successful pregnancy. Broader insurance coverage would likely lead to more patients attempting IVF and to more IVF attempts per patient, with consequent greater individual success. **Arkansas, Hawaii, Maryland, Massachusetts, and Texas have mandated that insurers cover IVF, although in limited fashion.**

The 3.0 million current civilian employees of the Federal Government are covered by 435 different health plans nationwide. The large, nationwide plans participating in the Federal Employees Health Benefits Plan (FEHBP) cover many traditional medical and surgical treatments for infertility, but exclude coverage of IVF, reversals of sterilization, and artificial insemination. Assuming that from 2,500 to 3,000 civilian Federal employees undertake an average of two IVF cycles each, extending insurance coverage under FEHBP for IVF would cost an estimated $25 million.

WHAT ETHICAL ISSUES ARE INVOLVED?

A wide range of conflicting established moral viewpoints makes the development of public policy related to infertility difficult. Where there are pluralities of viewpoints and a lack of any single established moral approach, uniform solutions are questionable.

Recent years have seen the appearance of several ethical analyses of reproductive technologies, with most leading to pronouncements that a particular technology is either ethically acceptable or not. In 1987, for example, the Roman Catholic Church issued its *Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation*. The Church supported basic medical and surgical treatment for infertility but opposed nearly all other techniques for diagnosing and treating infertility.

Similar analyses examine at least six themes:

- **The right to reproduce.** Procreation is seen by most as a fundamental facet of being human. Differing views about the relative im-

portance of procreation have spawned disagreement over how to balance a claim to reproduce against other needs. Critical unanswered questions are whether infertile couples have the right to use the gametes or bodies of others, and the right to financial assistance to obtain treatment they might not otherwise be able to afford.

- **The moral status of an embryo.** IVF and the ability to freeze embryos raise questions about appropriate treatment of embryos that are likely to be debated for some time to come. While some recognize embryos as full persons from the moment of fertilization, others claim an embryo has no moral status whatsoever. Still others contend embryos have significant moral standing, although not equal to that of a person. The unresolved debate about how to view and handle human embryos has impeded the growth of new knowledge about fertility, infertility, and contraception.
- **Bonding between parent and child.** Parent-child bonding is important both to parents and to the developing personality of the child. Conception that involves the efforts of a third party may redefine parenthood. The use of reproductive technologies raises questions about the minimum requirements for bonding and the meaning of parent-child relationships—and what they ought to be.
- **Research with patients.** Infertile patients have a right to know when treatment is a proven medical therapy and when it amounts to an experimental trial. Further, because of their often intense effort to conceive, infertile patients are particularly vulnerable to abuses of the researcher-subject relationship.
- **Truth-telling and confidentiality.** The intimate nature of infertility diagnosis and treatment and the use of donor gametes complicates simple ethical imperatives to tell the truth and to hold personal information in confidence.
- **Responsibilities of one generation to another.** Parents, physicians, and researchers have a duty to refrain from using reproductive technologies in ways that might harm future generations.

Most religious traditions in the United States view necessary medical or surgical treatments for infertility as acceptable and hold them to be desirable. There is general acceptance of the morality of artificial insemination by husband, considerable hesitation about artificial insemination by donor, and even less support for artificial insemination of single women. Most religions support IVF or gamete intrafallopian transfer using the married couple's own sperm and eggs as long as no embryos are discarded. Surrogate motherhood is largely opposed in any form.

WHAT DOES THE LAW SAY?

The U.S. Constitution has been interpreted to preclude almost any kind of governmental effort to prevent competent individuals from marrying and exercising their innate fertility. Yet there is no explicit statement in the Constitution of either a right to procreate or a right to privacy. Court decisions do not clearly state whether such rights extend to a right to obtain medical services, to use donor gametes, to use a surrogate mother, or to pay for these three avenues of overcoming infertility. Nevertheless, any governmental effort to regulate or ban any aspect of noncoital reproduction is certain to be subjected to judicial scrutiny.

Issues likely to be before the courts in the coming years include regulation of medical treatments using a couple's own gametes, restrictions on use of embryos not transferred, payment for undergoing medical procedures that carry some risk (e.g., ova donation), payment for embryos and their transfer, and the government's obligation to pay for or otherwise provide infertility services for poor people.

Noncoital reproduction introduces two prominent complications into family law, traditionally the domain of the States. First, when donor gametes are used, the legal identifica-

tion of a child's mother and father may come into question. A majority of States have already rearranged presumptions of legal paternity following the conception of a child by donor insemination. Some problems remain when the donor wishes to have some legal relationship with the child or when the recipient is unmarried. States have not yet begun to grapple with egg or embryo donation. These are more complicated because the gestational mother may or may not intend to raise the child. Therefore, models based on artificial insemination—which balance rearing and genetic paternity—are insufficient to cover cases requiring balancing of rearing, gestational, and genetic maternity.

Second, when extracorporeal embryos are at issue, questions arise concerning the legitimacy of actions with embryos (e.g., sale, transfer to nongenetic relations, or disposal) and, further, concerning who may make decisions concerning embryos. At least two State legislatures have considered the problems raised by extracorporeal embryos. Louisiana has tried to give them the legal status of a child—meaning, among other things, they cannot be sold or discarded—but the law has yet to face a constitutional challenge based on its possible conflict with related Supreme Court decisions.

Florida has outlawed the sale of embryos. This has not yet been challenged as an interference with the right to procreate. The question has largely been avoided as physicians have been careful to obtain the opinions and consent of the genetic parents before doing anything with an embryo. It remains unclear whether an embryo has status as the property of the genetic parents (meaning it can be disposed of as they please) or as analogous to that of a child of the genetic parents (meaning it is protected by State law from parental actions that are harmful), or some other status as yet unenunciated.

IS SURROGATE MOTHERHOOD HERE TO STAY?

Surrogate motherhood is more a social solution to infertility than it is a medical technology. It burst into American consciousness in 1987 with saturation media coverage of the *Baby M* case, when a woman changed her mind and wanted to keep the baby she bore, but was forced to yield the child to the biological father who had hired her. **The legal status of surrogate motherhood arrangements is today unsettled and likely to stay that way for some time to come.**

Surrogate motherhood may occur in two ways. A woman may be artificially inseminated with the sperm of a man who intends to be the rearing parent of the resulting child. Or a woman may be the recipient of a transferred embryo and carry to term a baby to whom she is genetically unrelated. The former procedure is far more common than the latter, although surrogacy involving embryo transfer could become more common in the future.

About 600 surrogate mother arrangements have been concluded to date. In a few of these, the participants indicated that they had either changed their intentions or been otherwise dissatisfied with the outcome. About 15 surrogate mother matching services are active in the United States, and as many as 100 surrogate mother arrangements may be concluded annually over the next several years. A typical contract involves a $10,000 fee to the surrogate mother and an additional $20,000 to $30,000 in living expenses, medical expenses, and attorneys' fees. In such a circumstance, about $1 out of every $4 actually goes to the surrogate mother. Contracts often impose restrictions on a surrogate's personal habits during pregnancy (e.g., smoking, alcohol consumption, exercise) and conditions for medical care (e.g., mandatory amniocentesis).

Legislation addressing surrogate motherhood has been introduced in more than half the State legislatures, and four States have passed laws. In 1987, Louisiana enacted legislation inhibiting surrogacy; in contrast, Arkansas has statutorily facilitated surrogate motherhood under some circumstances. Nevada exempted lawful surrogacy from its ban on baby-selling, and

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Kansas exempted surrogacy from prohibitions on advertising. State court decisions have consistently found surrogacy contracts to be unenforceable, even though they have split on whether the contracts are illegal.

In the absence of Federal legislation or Federal judicial decisions, State legislatures and courts are likely to continue to come to different conclusions about the desirability of commercialized surrogate motherhood.

WHAT REPRODUCTIVE HEALTH CARE DO VETERANS RECEIVE?

The Veterans' Administration (VA), the Nation's largest health care delivery system, offers only limited treatment for infertility in its 172 medical centers and 227 outpatient clinics. Since infertility treatment often involves the examination and treatment of both partners, and the VA has authority to administer medical treatment solely to veterans, the VA lacks authority to treat a nonveteran spouse of an infertile couple. Most important, **the VA does not classify infertility as a primary disability, thus severely limiting the treatment available to veterans.**

In 1985, about 16,000 male veterans and just over 1,200 female veterans had known service-connected medical conditions that could lead to infertility. ("Service-connected" refers to a disease, injury, or other physical or mental defect incurred during the time of active military service. It does not necessarily imply active combat.) Among the men, the conditions ranged from removal of the testes or prostate to spinal cord injury. Among the women, the conditions ranged from removal of the ovaries to inflammation of the fallopian tubes or cervix. The VA, however, performed few procedures related to infertility among these veterans.

Spinal cord injury, caused principally by battlefield trauma during wartime and vehicular and diving accidents during peacetime, is of special concern to both the VA (which supports 20 spinal cord injury centers) and veterans' advocacy groups. The current outlook for fertility after spinal cord injury in paraplegic men (although not women) is often poor. Erection and ejaculatory dysfunction, compounded by infections of the urogenital tract, are common. VA research on electroejaculation and vibration-induced ejaculation is likely to offer hope for fertility to veterans—and ultimately nonveterans—with spinal cord injuries. Ironically, even when sperm are obtained in this way by VA physicians, insemination of the veteran's nonveteran wife cannot be undertaken under VA auspices.

WHAT HAVE OTHER COUNTRIES DONE?

Eight other nations (Australia, Canada, Federal Republic of Germany, France, Israel, the Netherlands, Sweden, and the United Kingdom) have enacted legislation or issued major Government reports on the use of noncoital reproductive technologies. At least another 35 countries and four international organizations have had public debate, considered legislation, or examined some aspect of this issue.

Artificial insemination by husband and donor are generally considered acceptable techniques worldwide. Several countries have legislation stating that children resulting from artificial insemination by donor are the legitimate offspring of the woman and her consenting husband. IVF is generally considered acceptable, provided it is used only when medically necessary.

The use of artificial insemination and IVF by unmarried couples, homosexual couples, and single men and women is more controversial. The use of donor gametes in IVF is not universally accepted. Oocyte donation is not as widely accepted as sperm donation, largely because the technology is considered experimental. Acceptance of embryo donation varies widely.

Most controversial are the topics of surrogate motherhood and research on human embryos.

Countries that do approve embryo research often stipulate that embryos must be excess ones obtained through IVF, not created for research, and they often impose a time limit after which research must end (e.g., 14 days after fertilization). Surrogate motherhood has achieved little acceptance, and several countries have taken steps to ban the practice, especially its commercial use.

WHERE DO REPRODUCTIVE TECHNOLOGIES GO FROM HERE?

Speculation about reproductive technologies yet on the horizon has captured the public's imagination like few other aspects of infertility treatment, although new reproductive technologies are only one factor driving increased interest in infertility treatment (see table 2). The next decade will likely see proliferation of the practice of embryo freezing as an adjunct to IVF, although if success in freezing eggs comes about, that would obviate the need for most embryo freezing. Cryopreservation of eggs before fertilization, however, stands as a formidable technical task and may involve an insurmountable biological obstacle—damage to the fragile chromosomes of the oocyte.

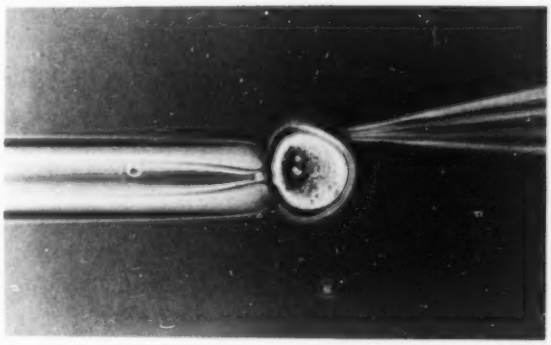


Photo credit: Martin Quigley

Micromanipulation of sperm into egg

Successful pregnancies following micromanipulation of a single sperm into an egg—recorded in neither animals nor humans, to date—would mark dramatic progress in the treatment of male infertility, most of which is caused by too few or abnormal sperm. Ethical and legal concerns regarding proper selection of one human sperm for fertilization may ultimately limit the application of this technology.

Techniques for screening sperm and ovum donors for a limited number of genetic anomalies lie in the foreseeable future. The practical application of genetic screening by practitioners of artificial insemination is uncertain, however, and no amount of screening will exclude all donors capable of transmitting genetic disorders.

Reliable separation of X- and Y-bearing sperm for sex selection remains elusive despite many attempts. When sex selection of human sperm cells becomes possible, its use will be limited by the willingness of couples to undergo artificial insemination or IVF.

Table 2.—Some Causes of Increasing Requests for Infertility Services in the 1980s

More couples with primary infertility	Increasing proportion of infertile couples seeking care	Increasing number of physicians providing infertility services	More conducive social milieu	Evolution of new reproductive technologies
• Aging of the baby-boom generation • Delayed childbearing; more people in higher risk age groups • Childbearing condensed into shorter intervals • Delayed conception due to prior use of oral contraceptives	• Decreased supply of infants available for adoption • Heightened expectations • Larger number of people in higher income brackets with infertility problems • Larger percent of infertile couples are primarily infertile	• Greater demand from private patients • More sophisticated diagnosis and treatment • At least 169 sites in the United States offering in vitro fertilization or gamete intrafallopian transfer	• Baby-boom generation expects to control their own fertility • Profamily movement • Increased discussion of sexual matters due to the AIDS epidemic • Extensive media coverage	• Artificial insemination • Surrogate motherhood • In vitro fertilization (IVF) • Gamete intrafallopian transfer (GIFT) • Cryopreservation

SOURCE: Adapted from S.O. Aral and W. Cates, Jr., "The Increasing Concern With Infertility: Why Now?" *Journal of the American Medical Association* 250:2327-2331, 1983.

The development and use of techniques to select the sex of human embryos are likely to be slowed because techniques developed thus far (for cattle) involve splitting embryos into one part for sexing and another part for transfer. Splitting or biopsying human embryos is certain to be a contentious issue.

One technology of the present, IVF, is itself a powerful means for unraveling mysteries of the human reproductive process. The advent of IVF permits researchers for the first time to view human reproduction in progress. Understanding the interactions between sperm and egg has potentially broad application not only for conception, but for contraception as well. Researchers seeking Federal funding to work in this area, however, have faced since 1980 the stifling effects of a de facto moratorium on Federal funding of research involving human IVF.

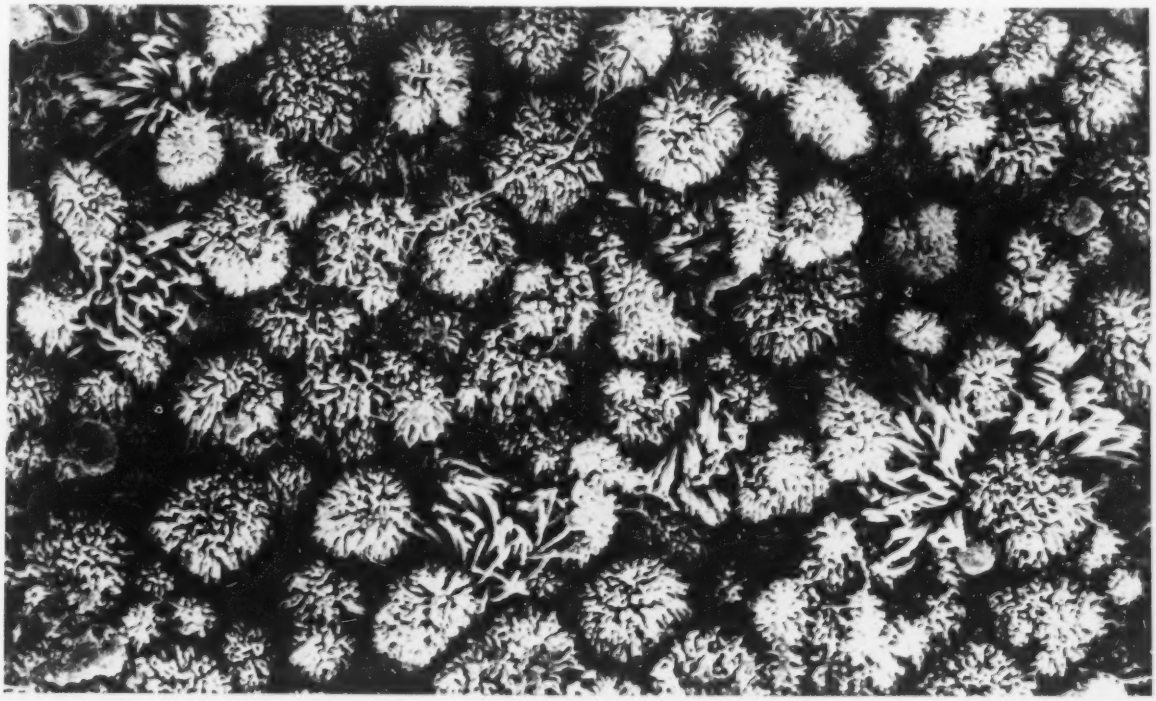


Photo credit: Walter H. Wilburn, Electron Microscopy Center, University of South Alabama

Endometrial cells lining uterus: site of embryonic implantation (3750× magnification)

POLICY ISSUES AND OPTIONS FOR CONGRESSIONAL ACTION

Nine policy issues related to infertility prevention and treatment were identified during the course of this assessment. They are:

- collecting data on reproductive health;
- preventing infertility;
- information to inform and protect consumers;
- providing access to infertility services;
- reproductive health of veterans;
- transfer of human eggs, sperm, and embryos;
- recordkeeping;
- surrogate motherhood; and
- reproductive research.

Associated with each policy issue are several options for congressional action, ranging in each

case from taking no specific steps to making major changes. Some of the options involve direct legislative action. Others involve the executive branch but with congressional oversight or direction.

The order in which the options are presented does not imply their priority. Moreover, the options are not, for the most part, mutually exclusive: Adopting one does not necessarily disqualify others in the same category or within any other category. A careful combination of options might produce the most desirable effects. It is important to keep in mind that changes in one area may have repercussions in others.

ISSUE: Should the Federal Government improve collection of data on reproductive health?

Federal support of collection of data on reproductive health is concentrated in two agencies of the Public Health Service: the National Institutes of Health (NIH) and the Centers for Disease Control (CDC), with its National Center for Health Statistics.

The Federal Government has an interest in collecting data in three areas of infertility: factors contributing to infertility, its prevalence, and the outcome of certain treatments. Few data are consistently collected on factors contributing to infertility at this time. An estimated 20 percent of infertility is a result of sexually transmitted diseases. Gonorrhea, one of the two sexually transmitted diseases known to lead to pelvic inflammatory disease (PID) and thus to infertility, is a reportable disease. But the other, chlamydia, is not. Chlamydial infection is now the most common sexually transmitted disease, and it has significant adverse reproductive consequences, particularly for women.

Nor do much data exist on the prevalence of infertility in the United States. The source most often cited is the National Survey of Family Growth (NSFG), a survey conducted periodically by the National Center for Health Statistics to collect data on fertility, family planning, and related aspects of maternal and child health. Surveys were conducted in 1976 and 1982, and another began in 1988.

There is some concern in the United States that the handling of embryos extracorporeally during IVF might result in increased numbers of birth defects or other health problems in the resulting offspring. NIH has conducted a short-term study of IVF babies born at the Jones Institute of Reproductive Medicine (Norfolk, VA), but no long-term followup is planned. NIH is beginning a study of women undergoing IVF, but this will not focus on the health of the resulting offspring. Thus, there is currently no systematic Federal method for registering the birth of IVF babies and for following the development and health of these individuals.

Option 1: Take no action.

Absent action to make chlamydial infection a reportable disease and thus commence a national surveillance system, researchers and the Government will continue to rely on data obtained from clinics, physician practices, and other health care facilities for estimates of prevalence and incidence of chlamydial infection.

NCHS expanded the questionnaire for the 1988 NSFG, adding more questions concerning infertility. Thus, available information on infertility will improve even without congressional action. The added questions will begin to fill in some of the gaps, such as more information on some factors contributing to infertility, on the prevalence of male infertility, and on infertility treatment.

If Congress chooses not to request monitoring of the health of babies resulting from IVF, the procedure's potentially harmful or beneficial effects on these babies may go undetected. Individual IVF clinics may conduct their own research, but as success rates and the methods of treatment can vary widely between clinics, such research would not be representative of all IVF clinics.

Option 2: Appropriate funds for the Secretary of Health and Human Services to make grants to State public health departments for the establishment of a national surveillance system on chlamydial infection.

A national surveillance system is crucial for control and prevention of chlamydial infection as it would provide quantitative estimates of incidence and prevalence, a basis for identifying infected

individuals and those at risk, and a tool for evaluating control efforts. Compared with the piecemeal reporting that now exists, a national system would allow the Centers for Disease Control and the various State health departments to identify high-risk groups and problem areas, thus enabling them to target their funds for screening and education in the appropriate populations and areas. The prevention and treatment of chlamydia that would result from these efforts would likely lead to lower rates of PID and thus to decreased rates of PID-related infertility.

A national surveillance system would require State reporting laws or regulations. Reporting laws not only provide accurate information on the extent and trend of the disease but also promote the involvement of public health authorities in assuring adequate individual patient management and in facilitating screening and education.

Although CDC has consistently recommended that the States establish this surveillance system, individual States are unlikely to do so without additional funds. Congress could appropriate funds for the Secretary of Health and Human Services to make grants to State public health departments, thus helping them handle the costs of making chlamydia a reportable disease.

Option 3: Direct the Secretary of Health and Human Services to enhance the collection of data on infertility.

Congress could direct the Secretary of Health and Human Services, through NCHS, to enhance data collection on infertility. One way this could be accomplished is by increasing the frequency of data collection through a followup telephone survey of the NSFG. Another improvement would be increasing the sample size of the NSFG.

Few data are currently available on male infertility that are based on information drawn from men themselves. NCHS plans to expand the NSFG to include information on the frequency of male infertility, but it will not obtain any information on the factors that lead to it, as the questions will still be addressed to women. To obtain such data on men, a completely different survey addressing men's reproductive health would be necessary. Thus, a third improvement to the collection of data on infertility would be adding a survey of male reproductive health.

Option 4: Establish a systematic method for registering the birth of IVF babies and for following the development and health of these infants.

For the first time in human history, babies are being born following extracorporeal fertilization. Although the incidence of birth defects following IVF does not appear to be disproportionately large, the absence of developmental effects of extracorporeal embryo culture (and perhaps freezing) is not a certainty. Congress could direct the Secretary of Health and Human Services to collect data on the health and development, including psychological development, of IVF babies from birth to maturity to assess the effects of these techniques. The need for such a study could be reevaluated periodically, and the safety and efficacy of other reproductive technologies (e.g., gamete intrafallopian transfer) could also be reviewed periodically. Documentation of good health among individuals conceived by IVF would carry the side benefit of ameliorating some public concern about the procedure.

Pursuit of this option has several costs, particularly as the offspring of assisted conception increase in number. Singling out these individuals for scrutiny raises ethical questions and may be viewed as an intrusion into their privacy. Moreover, the size and cost of such an effort is likely to grow rapidly. Finally, such monitoring forecloses the option of the parents not to reveal to the child the circumstances of his or her conception.

ISSUE: Should efforts toward prevention of infertility be enhanced?

The Federal Government supports no identifiable activities expressly directed toward prevention of infertility. It supports several activities allied with prevention of infertility, such as NCHS collection of descriptive data about infertile couples, contraceptive research funded by NIH and the Agency for International Development, and programs of the Centers for Disease Control that aim to prevent sexually transmitted diseases. Yet the link between these programs and the prevention of infertility has never been prominently

forged. As a result, efforts to prevent infertility are not well coordinated within the Federal Government.

Option 1: Take no action.

Under Section 318 of the Public Health Service Act (42 U.S.C. 247c), the Secretary of Health and Human Services, acting through the Centers for Disease Control, is authorized to make grants for the prevention and control of sexually transmitted diseases. Inasmuch as STDs account for an estimated 20 percent of infertility, the Secretary's authority could be used to support programs directed toward prevention of some infertility. Such activities have not been prominent, however, and in the absence of congressional action this situation is likely to continue. In addition, the bulk of infertility is not addressed by programs for prevention of sexually transmitted diseases and is not specifically addressed elsewhere by existing governmental authority.

Option 2: Amend the Public Health Service Act to extend the program of grants for prevention and control of sexually transmitted diseases to include prevention of infertility secondary to sexually transmitted diseases.

Congress could amend the Public Health Service Act to extend specifically the Secretary's authority to make grants for the prevention of infertility believed to be a consequence of sexually transmitted diseases. To be effective, such an extension of authority would need to be accompanied by additional appropriated funds. Amending the Public Health Service Act in this way would focus preventive efforts on the one important preventable cause of infertility identified to date. In addition, such congressional action would have the salutary symbolic effect of raising the apparent priority given to infertility prevention.

A disadvantage of such action is that it might appear to give disproportionate emphasis to STDs as a cause of infertility at the expense of identifying other causes and preventive measures. Pursuit of this option would not address prevention of the majority of cases of infertility, which are not linked to STDs. For those cases, prevention first requires additional research into the factors leading to infertility.

Option 3: Evaluate Federal efforts to prevent infertility.

Congress could direct the Secretary of Health and Human Services to report on Federal activities related to prevention of infertility. Because some efforts in reproductive research fall outside the purview of the Department of Health and Human Services, Congress could direct the Secretary to convene an interagency task force to assess preventive efforts. Or Congress could exercise oversight by means of hearings on this subject. Congressional evaluation of Federal efforts to prevent infertility is likely to identify a need for a coordinated effort that goes beyond prevention of sexually transmitted diseases to consideration of causes of infertility that are not well understood.

Option 4: Establish a demonstration project for identification of risks for infertility.

Beyond sexually transmitted diseases, there are many suspected factors contributing to infertility but few confirmed culprits. Congress could direct the Secretary of Health and Human Services to establish a long-term research effort aimed at identifying exposures or behaviors in young adulthood that predispose an individual to infertility. Such long-term, longitudinal research that follows young adults through their reproductive lives is difficult, expensive, and often exceeds the active research lifespans of individual investigators. In instances like this, therefore, coordinated, cooperative efforts (e.g., the Framingham Heart Study) are required. Such a study is critical for ferreting out confirmed from suspected factors contributing to infertility, and is likely to be a prerequisite to organizing serious programs to prevent whatever portion of infertility can be prevented.

Without a comprehensive longitudinal study to identify risk factors for infertility, many of them may never be fully defined and possible preventive steps may never be taken. On the other hand, the result of such an undertaking may be confirmation that a number of cases of infertility are of unknown origin and not preventable.

Option 5: Enhance education in reproductive health.

Education about reproductive health, as with most education in the United States, is the responsibility of local jurisdictions and largely excluded from the Federal purview. Knowledge of reproductive health is erratic and uneven among individuals of reproductive age; many myths and half-truths are believed as fact. This situation can have important consequences for preventing infertility.

Congress could take at least two steps to enhance education in reproductive health. First, Congress could exercise oversight to see that the Secretary of Health and Human Services, under Title X of the Public Health Service Act, directs health clinics receiving Title X funds to bolster the infertility services offered to their patients. More than 4,000 clinics in the United States serve about 4.3 million people each year. Infertility services constitute about 1 percent of the clinics' activities. This existing network of clinics could make available educational materials and counseling, for example, about the potential long-term infertility consequences of some family planning methods.

Second, Congress could direct the Secretary of Education to develop a model curriculum for primary, secondary, and postsecondary students that illustrates fundamental facts about reproductive health and prevention of infertility. Although it has long been objectionable to some segments of American society, education in reproductive health may be the most cost-effective means at the disposal of the Federal Government for making long-term progress in preventing infertility.

ISSUE: Should the Federal Government ensure that consumers of selected infertility services have the information to make informed choices?

Congress generally does not regulate medical practice, with the exception of drawing broad criteria for care delivered at Veterans' Administration hospitals or reimbursed by Federal insurance programs. Nor are medical techniques subject to consumer protection legislation, with the notable exception of Food and Drug Administration regulations for testing drugs and devices, and for regulating advertising of their indications and efficacy. Rather, quality assurance and consumer protection issues are left to State legislatures, professional societies, consumer groups, and word-of-mouth. However, some have suggested that the Federal Government take steps to ensure that infertile individuals are made aware of the efficacy of the treatments offered and of the success record of medical personnel with whom they are consulting.

This has been particularly stressed with regard to IVF, for several reasons:

- Aspects of the technique are still to some extent in a research phase.
- Success rates vary considerably.
- Success rates are reported in various, and sometimes confusing, ways.
- The procedure is carried out at times in free-standing clinics or other settings that are not subject to all the usual hospital peer-review practices.
- Relevant professional societies do not yet have accreditation programs directed specifically at IVF.
- As the procedure can entail months of drug treatment and repeated surgeries, it can represent a serious health risk and constitutes a major disruption of personal and professional activities.
- IVF is often excluded from insurance coverage, and so may be very costly to individuals.
- The patient population for these services is particularly vulnerable because it largely consists of individuals who have tried for many years to have a much desired pregnancy.

Option 1: Take no action.

Congress could leave quality assurance and consumer protection efforts in the area of infertility services to the individual States and medical professional societies. Other medical services, such as novel techniques for cancer therapy, have similarly suffered from varying success rates and vulnerable patient populations. Absent Federal action, it can be expected that State quality control legislation (such as that enacted in Louisiana), consumer education by private organizations, and medical society activity will attempt to protect patients from the risk, pain, disruption, and cost of undergoing the procedure at clinics or hospitals without a demonstrable success rate. But such efforts will inevitably be spotty for at least the next several years.

By taking no action, Congress would avert bringing public scrutiny to a very private area of health care. It is possible that Federal regulation of infertility services could change the character of those services. Gamete donors, for example, may be unwilling to participate, and recipients of gametes or embryos may be uneasy about medically assisted conception conducted in the spotlight of Federal regulation.

Option 2: Encourage the use of a consensus review or conference on the use of IVF, gamete intrafallopian transfer, and other innovative treatments for infertility.

Short of regulating infertility treatment and research, Congress could facilitate greater data collection and voluntary adherence to guidelines developed by professional societies. This can be done by authorizing the use of governmental agencies or commissioning resources for efforts by professional societies, research institutes, or the insurance industry to hold consensus conferences and to recommend protocols for high-quality care. A consensus conference, for example, could be used to evaluate patient data and to recommend a protocol that lists the best indications for the use of IVF as opposed to gamete intrafallopian transfer. Conferences and reports could also be used to help define a "successful" program; to distinguish experimental techniques, techniques with some possibility of success, and standard techniques; and to make more uniform the minimum level of staffing for a program.

Congress could exercise oversight to encourage NIH or the National Center for Health Services Research and Health Care Technology Assessment to review or hold a consensus conference on innovative infertility treatments. NIH consensus conferences—of which more than 60 have been held in the last decade—could be used to:

- influence the development of data collection on the use of IVF, gamete intrafallopian transfer, and other reproductive techniques;
- recommend indications for use;
- establish conventions for reporting successful outcomes; and
- define standards for laboratory equipment and personnel training.

One important consideration regarding the appropriateness of an NIH consensus conference is whether the questions concerning the medical technology are primarily scientific and clinical, or primarily ethical or economic. The NIH conferences focus on the former. The Office of Health Technology Assessment of the National Center for Health Services Research and Health Care Technology Assessment, under the Office of the Assistant Secretary for Health, has authority to undertake review of less scientific issues, such as safety, efficacy, cost effectiveness, and indications for use of infertility treatments.

Congress could also commission a private research institute or professional society to review current practice of selected infertility treatments and to recommend indications for use, protocols for patient selection, and minimal personnel staffing for clinics. Among the many nongovernmental entities with the resources to perform this function are the American Medical Association, the Blue Cross/Blue Shield Association, and the Institute of Medicine at the National Academy of Sciences.

Option 3: Extend consumer protection laws to selected infertility services.

Congress could direct the Federal Trade Commission to exercise its authority under Section 5(a)(6) of the Federal Trade Commission Act to examine whether advertisement of success rates at various IVF or gamete intrafallopian transfer clinics is misleading, and, if so, to issue appropriate regulations. Regulations could be issued, for example, to standardize the ways in which success rates are reported, so that individuals are better able to make an informed choice about whether and where to undergo a procedure.

Even such consumer regulation is not an effective means of directly regulating the quality of the services offered, however. Regulating a medical service itself—for example, by setting standards for personnel and facilities—would be an unusual step, as such regulation does not generally take place at the Federal level, with the exception of setting quality control standards for Medicare reimbursement.

ISSUE: Are existing mechanisms for gaining access to infertility diagnostic and treatment services adequate?

Currently, those who can afford to pay for infertility services out-of-pocket have the greatest access. To consider use of newer medical technologies, infertile individuals need to be able to pay anywhere from several hundred dollars to more than $22,000. Individuals with some private insurance coverage generally can expect to have a large portion of their expenses covered during the diagnostic phase, with considerable variability of coverage for infertility treatments. Although the majority of health insurance plans have specifically excluded coverage for IVF treatment, there may be a significant amount of reimbursement for the various components of such treatment (e.g., laparoscopy).

Under the Federal Medicaid Program, it is possible to receive reimbursement for infertility diagnosis and treatment if a person is designated as categorically needy and if the State has a policy to submit claims for the reimbursement of infertility diagnosis and treatment services under the heading of "family planning services." States are currently shifting away from the practice of submitting such claims as family planning services.

Under the Federal Medicare Program, it is possible to receive reimbursement for infertility diagnosis and treatment if a person has received Social Security disability benefits for more than 2 years and thus becomes entitled to Medicare coverage. It is not clear how many disabled individuals of reproductive age have actually sought or received this coverage.

There are geographical as well as financial determinants of access to infertility diagnosis and treatment. For the initial medical consultation regarding this problem, couples are most likely to seek the advice of their gynecologist, general practitioner, or urologist. If the problem is serious enough for referral to an infertility specialist, access to such care is likely to be reduced. Sophisticated infertility care is generally located in urban areas. Innovative, experimental procedures for more difficult infertility cases are more likely to be available at universities and medical centers.

Option 1: Take no action.

If Congress takes no action, then access to physicians and diagnostic and medical care for infertility will continue to be determined by individual financial resources and geography. This may lead to an inequitable distribution of infertility services among socioeconomic classes or geographical areas. On the other hand, by taking no action Congress will avoid imposing upon some citizens a responsibility to support certain medical procedures they may consider purely elective or immoral.

Option 2: Direct the Health Care Financing Administration of the Department of Health and Human Services to review and report on the extent of existing coverage for infertility diagnosis and treatment services under the Medicaid and Medicare Programs.

Current reporting schemes under Medicare and Medicaid do not identify which diagnostic and therapeutic infertility procedures are covered and how much they cost. This information would provide an important basis for decisions about any changes needed in the Medicaid and Medicare Programs.

Option 3: Amend the existing Federal Medicaid Program to add a new reimbursement category for services related to the diagnosis and treatment of infertility.

Amending Medicaid coverage would establish consistent national policy for infertility diagnosis and treatment coverage. It would no longer be at the discretion of the States to decide whether or not to submit claims for reimbursement of infertility services under the heading of "family planning services." This change in Medicaid reimbursement policy would likely result in increased demand for reimbursements for infertility services. It could also be viewed as equivalent to a finding of ethical acceptability or unacceptability by the Federal Government with regard to each procedure allowed.

Option 4: Amend Title 5 of the U.S. Code to provide that any carrier offering obstetrical benefits under the health benefits program for Federal employees shall also provide benefits for

medical procedures to overcome infertility, including procedures to achieve pregnancy and to carry pregnancy to term.

Insurance programs for Federal workers could be required to cover all diagnosis and treatment of infertility. The existing Federal Employees Health Benefits Program covers the costs of pregnancy and delivery and some forms of infertility diagnosis and treatment. Less traditional techniques, such as IVF, gamete intrafallopian transfer, and artificial insemination, arguably merit similar coverage. Although such legislation would benefit only the Federal work force, it could serve as a model to private insurers and employers. Such a model would provide a database of cost information upon which private plans could be constructed.

Implementation of this option could cause some insurance carriers to drop obstetrical benefits entirely. Those carriers who expand their coverage would likely increase the premiums charged Federal employees and the Government.

Option 5: Facilitate adoption, a social alternative to infertility treatment.

Some couples seek medical or surgical treatment, or a surrogate mother, because adoption is for them too difficult or time-consuming. Adopting through a public agency can entail a wait of 2 to 10 years and stringent eligibility criteria; private, independent adoption can be expensive and take from 6 months to 5 years. Congress could work to facilitate adoption by examining the results achieved under the Adoption Assistance and Child Welfare Act of 1980, the Title IV funding of child welfare (including foster care) and adoption assistance under that act, and the 1978 Child Abuse Prevention and Treatment and Adoption Reform Act. These programs could be used to develop a national database of adoptable children for use by couples seeking private adoption, as well as to remove barriers to the adoption of children with physical or mental handicaps, older children, or children of a different race.

Many available children in this country are never adopted because individuals find the prospect of an interracial family, a difficult adjustment period for an older child, or a lifetime of care for a handicapped child to be too daunting. Further incentives and social services could be used to help ease these difficulties, and better use of a national clearinghouse for all adoptable children may make the process of adoption, even if lengthy, more manageable and successful. Even with more services, however, such adoptions are not likely to be attractive to all individuals seeking to form a family. For some, the purpose in seeking infertility treatment or a surrogate mother is to have a child who is genetically related to at least one parent. Adoption cannot satisfy this desire.

Photo credit: Library of Congress

ISSUE: Should the Veterans' Administration provide infertility diagnosis and treatment?

For the VA to provide care to a veteran, at least four conditions must be met: the veteran must have a disability, the VA care must be for that disability, the care must be necessary, and the care

must constitute hospital care (including medical treatments). These provisions mean that veterans currently obtain only limited treatment for infertility from the VA.

During the 100th Congress, on Dec. 4, 1987, the Senate passed an amendment to Section 601(6) of Title 38 of the U.S. Code. This would give the VA authority to provide "services to achieve pregnancy in a veteran or a veteran's spouse where such services are necessary to overcome a service-connected disability impairing the veteran's procreative ability." A similar provision had been passed by the Senate (but not the House of Representatives) during the 99th Congress.

Option 1: Take no action.

The present position of the VA prevents it from treating infertility since the agency does not interpret infertility to be a disability (defined as a disease, injury, or other physical or mental defect). Although some infertility medical workup may be performed, procedures such as IVF, gamete intrafallopian transfer, and artificial insemination may not be provided. In addition, the VA lacks authority to treat a nonveteran spouse for infertility.

Financial arguments for taking no action are supported by the fact of the aging of the veteran population—increased expenditures by the VA for costly and elective medical procedures may not be justified. If additional funds are to be allocated to the VA for health care, these funds might best be used to improve and expand treatment of life-threatening disorders. Further, taking no action means the VA need not make judgments about fitness for parenting.

On the other hand, the comparatively small number of veterans with service-connected infertility means the VA would not incur substantial expenses in contracting for infertility services. In addition, the VA's mission is to provide health care to eligible veterans. This health care is not limited to life-threatening disorders, as evidenced by the wide range of services the VA already provides.

Option 2: Direct the Administrator of the Veterans' Administration to interpret disability to include the inability to procreate.

If Congress proceeds with this action, the Veterans' Administration could offer infertility treatment under existing statues and regulations without other specific legislation. Treatment of the nonveteran spouse, however, would remain beyond the authority of the VA. Therefore, treatment of infertility under this option would probably be restricted to specific cases of infertility where the disorder was found solely in the veteran partner. This option would still permit the VA to proscribe particular infertility treatments as being experimental or too expensive, and to limit its coverage to traditional medical or surgical therapy.

In a variation of this option, Congress could elect to mandate that infertility be considered by the VA a secondary disability or an inevitable consequence of disease and therefore compensable. Infertile veterans could then obtain some funds to be treated privately.

Option 3: Amend Title 38 of the U.S. Code to specify that infertility treatments including but

Photo credit: U.S. Department of Commerce, Bureau of the Census

not limited to IVF, gamete intrafallopian transfer, and artificial insemination may be provided by the Veterans' Administration.

These treatments could be made available only to veterans with service-connected infertility but not their spouses, only to veterans with service-connected infertility and their spouses, to all infertile veterans but not their spouses, or to all infertile veterans and their spouses. Forms of infertility treatment that do not require hospital care especially require authorization through legislation, as VA regulations preclude such outpatient treatment. The disadvantage of this course of action is that any listing of infertility services may be viewed as exclusive and may not encompass emerging technologies.

The VA could administer such treatment in several ways. Infertility treatment units could be set up in all VA medical centers and offer services such as hormonal workup, semen analysis, fertility drugs, IVF, gamete intrafallopian transfer, artificial insemination, and other reproductive technologies. Since many of these services and treatments are not presently offered by VA medical centers, this option would involve a major commitment of funds to hire new staff such as gynecologists, reproductive endocrinologists, andrologists, reproductive tract microsurgeons (where surgical facilities are available), and laboratory personnel. The VA's relationship with medical schools would be affected in that new affiliations would be needed, for example, with departments of obstretrics and gynecology.

A limited number of regional or district infertility treatment centers could be set up in various VA Medical Centers, depending on the need. As with the preceding approach, this would involve hiring new staff and setting up infertility diagnostic and treatment laboratories. This would probably be most successful if regional infertility centers were established in VA hospitals closely associated with academic or medical institutions with programs for infertility treatment.

The VA could contract with other health care providers that have infertility treatment programs for the treatment of eligible veterans with infertility problems. Contract health care already exists within the VA for medical treatments such as gynecological services not generally available in a VA center. In addition, contract health care may be provided if VA facilities are not within a reasonable geographical distance. However, under the provisions for contract health care (38 U.S.C. 608), the eligibility for treatment is more limited than in VA facilities.

The VA could provide infertility treatment in some cases as part of the Civilian Health and Medical Program of the VA (CHAMPVA). This program provides health care for survivors and dependents of certain veterans. The criteria for eligibility are that the veteran must have a total disability, permanent in nature, resulting from a service-connected disability. The disability rating must be 100 percent. This approach would most likely provide benefits to a very limited population, although it may benefit veterans with spinal cord injuries since these individuals are classified as having total or near-total disabilities.

It is important to note that CHAMPVA provides the same health care benefits as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). These benefits include coverage of most types of infertility diagnostic and treatment procedures. Under CHAMPUS, however, artificial insemination, IVF, and gamete intrafallopian transfer are specifically excluded, as are any treatments that involve artificial conception. Although this approach may allow for the medical treatment of nonveteran spouses, other changes in CHAMPVA eligibility and benefits may be needed.

Lastly, Congress and the VA could provide infertility treatment for veterans by making available a one-time voucher or grant to infertile couples for the cost of procedures such as artificial insemination, IVF, and gamete intrafallopian transfer. These treatments would then be obtained from health care providers other than the VA. In most cases, grant-type benefits operate on an actual expense basis, with the VA either paying the bill directly or reimbursing up to a maximum amount. Questions that arise with this approach include the amount of the grant, and the responsibility of the VA to the couple and the offspring.

ISSUE: Should the transfer of human gametes and embryos be regulated?

Sperm are sold by commercial sperm banks throughout the United States and have been for many years. The Food and Drug Administration has authority, within its Center for Devices and Radiological Health, to regulate tissues, including semen. In 1988, FDA and professional societies involved in artificial insemination laid out new standards regarding storage and use of semen to protect semen recipients from infection with human immunodeficiency virus.

Donation of unfertilized ova is today occurring at a number of infertility clinics. A few have begun to pay women to undergo hormone stimulation and ovum retrieval, sometimes in the course of voluntary sterilization by tubal ligation. Ovum banking using frozen ova has yet to become available, but considerable research is under way to make this feasible.

Embryos that remain after IVF procedures are not yet sold, as clinics and hospitals have chosen instead to give parents the choice of having them frozen, destroyed, or donated. No technological obstacle exists to maintaining commercial embryo banks, although there is still a significant rate of embryo loss associated with freezing.

Option 1: Take no action.

Taking no action regarding the transfer of human gametes and embryos would be in keeping with the strong tradition of nonintrusion of the Federal Government into reproduction. If Congress takes no action, the majority of sperm banks will probably continue to pay donors for their semen and to charge recipients for the sperm. Screening of donors for genetic and infectious diseases will continue to vary among sperm banks, influenced by the periodic promulgation of standards by various professional medical societies, and inconsistently regulated by State laws.

Commercial embryo banking may develop, and guidelines for selecting recipients and setting prices could follow the model of sperm banking. State laws may be passed affecting the circumstances of the sales, such as provisions concerning recordkeeping, anonymity, or pricing, while other States may pass legislation banning the sales altogether. It is not certain whether such bans would withstand constitutional challenges based on State interference with the right to procreate.

Option 2: Mandate national standards for protection of paid ovum donors.

Although sperm donation entails no appreciable physical risk to the donor, ovum donation requires either abdominal surgery or sonographic-guided oocyte retrieval, both of which entail some added risk of infection and other complications to the donor. Women who donate extra eggs in the course of their own infertility treatment face no added risk.

Congress could enact legislation or direct the Secretary of Health and Human Services to issue regulations to protect ovum donors by requiring, for example, that commercial sales of ova (or embryos) be allowed only with ova obtained during a therapeutic or diagnostic procedure. This would effectively bar the development of a pool of women who are paid to undergo a medical procedure of some risk, when that procedure has no ancillary benefit to themselves.

Some may object that such a bar would be discriminatory, as men could continue to earn money by selling their sperm. Further, barring adult women from doing this may be seen as inconsistent with the fact that they can choose to be paid for other, more physically dangerous tasks.

Option 3: Mandate national standards for protection of recipients and offspring.

Congress could enact legislation directing the Secretary of Health and Human Services to set minimum standards for screening egg and sperm donors for serious genetic disorders and infectious diseases that could be passed on to recipients of their gametes or the resulting children. National standards could be based on adoption of existing professional society guidelines, with periodic reexamination of the efficacy of tests for human genetic disorders. Even if such standards were directed only at commercial gamete and embryo banks, they would provide significant guidance as to the minimum standard of care that ought to be met by unregulated providers, such as individual physicians.

Some may assert that national standards are likely to take longer to develop and to revise than those produced periodically by professional medical societies. Further, development of effective standards would probably require some kind of reporting and enforcement mechanism, unless the standards are to be used only to create a presumptive standard of care for use in individual cases of medical malpractice litigation.

Congress could also facilitate the development of a national databank on gamete donors (as South Africa has done), so that the number of donations from any one person could be limited. This could avoid the problem created when a single donor is used to initiate a large number of pregnancies, introducing some risk of unintended consanguinity among future marriage partners. This is of concern mainly in areas in which there are few donors supplying sperm for a geographically isolated population.

Further, the databank could be used to allow gamete banks to share information on the genetic and physical health of donors. Combined with followup reporting on the offspring, such record-keeping practices could also facilitate identification of donors shown to suffer from previously undetected genetic disorders, making it possible to prevent those persons from again selling gametes.

Reports in several other countries have recommended that the number of donations per donor be limited. In France, sperm banks keep strict records and limit the number of donations per person. The central organization of the sperm banks in France, however, is quite different from the large number of independent banks in the United States. The Warnock Committee in the United Kingdom proposed the most comprehensive plan, recommending that there be a central registry of donors that must be checked every time a clinic accepts a donor. South Africa does this by law. Any registry of donors carries the risk that it will decrease the willingness to donate of those individuals who prefer anonymity.

Option 4: Ban commercial sales of embryos.

Congress could amend the National Organ Transplant Act to outlaw the buying or selling of embryos. Some view the sale of embryos as making the human body a commodity and therefore unacceptable. Others view the sale of embryos as the unacceptable commercialization of a genetic blueprint. Embryos are generally viewed as deserving especially respectful treatment, and sales of embryos offends many persons who find it too close to the sale of babies or who fear that embryo sales may lead to classification of some embryos as more desirable than others. Further, permitting the sale of embryos could in some cases lead donors to undertake medical risks for pay.

On the other hand, such a ban could be viewed as an intrusion that limits the freedom of donors to engage in commerce. Further, a ban on commercial sales of embryos may be subject to constitutional attack as State interference with the right to procreate.

A ban on commercial sales of embryos will not necessarily greatly reduce the supply of gametes. Some countries, such as France, do ban such sales, and yet have managed to maintain successful sperm donation programs. Nevertheless, the U.S. market economy and culture may make such comparisons inappropriate.

ISSUE: Should anyone accepting or transferring human gametes keep nonidentifying genetic records on behalf of the potential child?

Donation of human gametes is usually accompanied by an oral patient history including important genetic information that can become a formal written record. Such information is routinely obtained by those who operate sperm banks as they screen donors. Currently, however, the type of information that is collected and the ways in which it is maintained and transferred vary greatly. This variation is particularly significant because the predictive value of genetic history may increase in coming years.

Option 1: Take no action.

If Congress takes no action, the transfer of such information will continue to occur in an occasional manner, and children born as a result of reproductive technologies that make use of donor gametes (i.e., IVF, gamete intrafallopian transfer, arti-

ficial insemination by donor, and surrogacy) will not have access to genetic information that might be vital to their health.

On the other hand, the medical community has not achieved consensus on the utility of minimal information about individuals' genetic heritages. The ethical and financial costs of collecting genetic information about gamete donors must be weighed against its ultimate usefulness.

Absent any congressional action, individuals who obtain or transfer human gametes (or embryos) may or may not adhere to the recommendations of professional associations such as the American College of Obstetricians and Gynecologists and the American Fertility Society to maintain a permanent record of minimal genetic screening information. The AFS's 1986 recommendations for a minimal genetic screen of gamete donors specify that practitioners maintain a permanent record that preserves confidentiality. The record should include the genetic workup and other nonidentifying information and should be made available on request—on an anonymous basis—to the recipient or resulting offspring.

Concerns about establishing a child's genetic endowment should be viewed in an important context: Some children born of married couples who did not use medically assisted conception were not sired by the father of record.

Option 2: Mandate that operators of sperm, ova, and embryo repositories, or anyone who transfers these materials, maintain written records detailing the nonidentifying genetic history of all gamete donors and that this information be available to the recipients of gametes or embryos and the eventual offspring.

If Congress were to enact such a law, or simply encourage standardization of recordkeeping on a voluntary basis, it would result in retention of information that currently may be lost or deliberately discarded in the interest of protecting the anonymity of gamete donors. It would reduce the extent to which some members of future generations may suffer from genealogical bewilderment resulting from the inaccessibility or loss of important information about their genetic endowments.

Such a law would somewhat increase the recordkeeping of those who are currently involved in the storage and transfer of human gametes and embryos, although much of this information is already being collected. Although much pertinent genetic information is already obtained in the process of screening potential gamete donors, the enactment of a new law would result in an increased recordkeeping burden for all such individuals. The occasional practice of mixing sperm from more than one source would also increase the complexity of such recordkeeping.

More complicated variations of this course of action include maintenance of white blood cells from gamete donors as a complete and retrievable genetic record, and recordkeeping with information that identifies the gamete donors. Both raise serious concerns about logistics and privacy.

ISSUE: Should commercialized surrogate motherhood be regulated by the Federal Government?

Surrogate motherhood is an infrequent but increasingly popular arrangement used by infertile couples, singles, and homosexuals as an alternative to adoption and perhaps infertility treatment in their efforts to form a family. Surrogacy arrangements are based upon principles of contract and family law, and therefore are largely within the traditional domain of State legislative activity.

With surrogacy an interstate business, Congress has the power under the Interstate Commerce Clause of the U.S. Constitution to enact regulatory legislation, but, just as with respect to interstate adoption activity, Congress may choose to leave this area primarily to State and local oversight. Coordination of State legislative efforts has not taken place, with the exception of activities of committees of the National Conference of Commissioners on Uniform State Laws and of the American Bar Association.

Option 1: Take no action.

Absent Federal direction, surrogate motherhood is likely to be subject to extensive State legislative debate and action over the next few years. State legislation, when enacted, is likely to vary con-

siderably, ranging from complete bans to only minimal oversight of contractual arrangements. This period of State legislative activity may be a useful experiment for finding a workable legislative scheme to either ban or promote the practice. Or lengthy and complicated custody battles could ensue if courts must first decide which State's law applies to the case (so-called choice-of-law questions). The problem can become particularly acute if the choice of using one State's law rather than another's could essentially decide the case. Lengthy custody suits are troubling because it becomes progressively more difficult to remove the child from his or her initial home, regardless of the merits of the case. Numerous custody battles may exact a heavy toll on the families and children involved.

Option 2: Review developments in State law related to surrogate motherhood.

Congress could exercise oversight to examine the trends in State law regarding surrogate motherhood to ascertain whether Federal action is necessary. Topics of interest could include State legislation and case law on resolution of custody disputes; development of standard contract provisions, including provisions relating to a surrogate's choice of diet, medical care, and pregnancy continuance; fee structures; and protection for offspring in the event of death or disability of an adult participant.

Option 3: Facilitate development of State legislation related to surrogate motherhood.

Congress could authorize the use of challenge grants to encourage States to explore approaches to surrogate motherhood. Funds could be used to finance studies of proposed legislation; to begin pilot projects for licensing of professional surrogate matching services or review of surrogate contracts; to determine the need for home studies of couples seeking a surrogate mother; or to carry out research concerning the psychological impact of surrogacy arrangements on a child, any siblings, and the adult participants.

Option 4: Facilitate interstate cooperation and harmonization of State laws.

Congress could facilitate joint efforts by States to develop a uniform approach to surrogate

Photo credit: Library of Congress

Surrogate mother matching service

motherhood. Congress could pass a joint resolution, for example, calling on States to adopt one of the model laws now being developed by various professional groups, such as the American Bar Association or the National Conference of Commissioners on Uniform State Laws. Congress could also draft such a model law itself, to be published in the Federal Register, as was done in a 1981 effort to harmonize State adoption laws with respect to children with special needs.

Although neither a joint resolution nor model legislation is binding upon the States, either could be used to express the sense of Congress concerning the use of surrogate motherhood. Congress could also encourage States to develop interstate compacts in order to avoid difficult choice-of-law problems in the event of a custody dispute surrounding an interstate arrangement, and to harmonize regulations concerning surrogate mother matching and child placement. The Interstate Compact on Placement of Children provides a precedent for the use of such compacts in the area of family law, in that case with respect to placing children in foster care or adopting homes.

Option 5: Mandate national standards for surrogate motherhood arrangements or commercial intermediaries.

Congress could enact legislation directing the Department of Health and Human Services to set national standards for the practice of matching

surrogate mothers to individuals seeking to hire them, or for the arrangements themselves. Such standards could include medical or psychological screening for surrogates and prospective rearing parents; recordkeeping requirements to allow children access to medical or personal data on their genetic and gestational parents; limitations on advertising techniques, referrals, and fees; and licensing requirements for the commercial intermediaries. These standards could also include limitations on the substantive provisions of the contracts professionals might offer to the participants. Limitations might include provisions concerning the restrictions placed upon the surrogate's lifestyle, choice of medical care, or right to terminate her pregnancy, and those concerning presumptions of custody.

Some argue that, as with regard to adoption, such regulation is best left to individual State legislatures. Others assert that as an interstate business, and potentially international business, surrogate mother matching is an appropriate subject of Federal attention.

In lieu of Federal licensing legislation or regulations, Congress could exercise its spending power to attach conditions to the receipt of Federal funds to require States to license professional surrogate matching services. For example, conditions could be attached to Federal funding for Aid to Families with Dependent Children, family planning agencies, or adoption assistance programs. Some of these programs are heavily dependent on Federal funding, and many States would probably feel compelled to pass the necessary legislation.

Absent Federal action, a patchwork of State legislative limitations and State court decisions is likely to influence the substantive content of surrogacy contracts and the persons able to use them.

Option 6: Facilitate international agreements concerning transnational surrogacy arrangements.

Already in the brief history of commercialized surrogate motherhood, women from other countries have contracted with American women to act as surrogates, and vice versa. This may become more common in the future. Gestational surrogacy (i.e., where a woman carries a child to whom she is genetically unrelated) may also become more common. Affluent couples, for example, could hire women from developing nations, for whom a fee of far less than $10,000 would still constitute a considerable sum.

To ensure that there is no confusion concerning the rights of these women, and to avoid conflicts of national law concerning maternity and child custody in the event of a dispute, Congress could work to facilitate international cooperation and agreement on transnational surrogacy arrangements. This could be accomplished by submitting proposals to amend one of the existing child welfare agreements (e.g., the Hague Convention on International Parental Kidnapping), in order to state clearly who, at least initially, shall be considered the mother and the father of a child, and who shall have initial rights to physical custody.

Option 7: Ban commercialized surrogate motherhood.

Congress could enact legislation to ban for-profit surrogate motherhood, leaving individuals able to engage in the practice as long as no money beyond actual expenses changed hands. Such a ban would probably have the effect of drastically reducing the scope of the practice. It would, however, be subject to constitutional challenge by those who assert that paying a surrogate mother is a protected aspect of reproductive liberty.

Alternatively, Congress could outlaw commercial intermediaries while leaving individuals free to make their own arrangements even if they involve payments to the surrogate. This too would probably reduce the scope of the practice. And while the same constitutional challenge could be mounted, it would be somewhat more difficult to maintain.

Bans on payments to surrogates or intermediaries or both could be designed as either civil offenses (for which one pays a penalty) or criminal offenses (for which one can be fined or jailed). Criminal penalties, particularly if directed toward the individual surrogates and couples, are likely to engender the most serious judicial challenges.

It is possible that any attempt to ban surrogate motherhood may drive the practice—which in

some cases can be done without doctor or lawyer —underground. This may reduce the frequency of the practice, but increase the medical and legal risks to the participants.

ISSUE: Do some areas of reproductive research require additional support?

Federal support of human reproductive research is concentrated in two agencies of the Public Health Service: NIH (in particular, the National Institute of Child Health and Human Development and the National Institute of Environmental Health Sciences) and CDC (in particular, the National Institute for Occupational Safety and Health and the National Center for Health Statistics). In addition, the National Science Foundation, the Environmental Protection Agency, the U.S. Department of Agriculture, the Department of Defense, the Department of Energy, the Agency for International Development, and the VA fund reproductive research involving humans or animals.

Option 1: Take no action.

In the absence of any targeted congressional action, research in broad areas of human and animal reproduction will continue to be supported by the Federal agencies listed. Research in male reproductive biology has historically lagged and will likely continue to do so in the absence of a special compensatory effort.

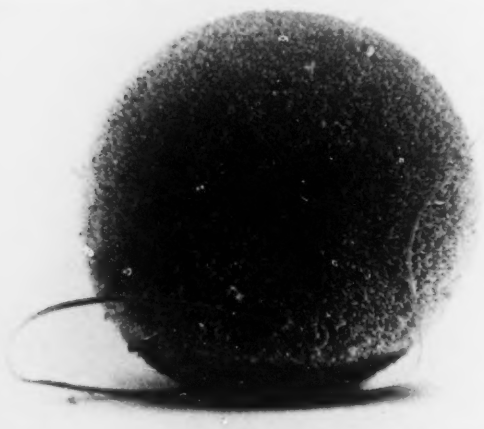


Photo credit: David M. Phillips

Rabbit sperm fertilizing rabbit egg

Research that involves fertilization of human sperm and eggs is today in effect excluded from Federal support because of the absence of an Ethics Advisory Board (EAB) within the Department of Health and Human Services; such a board is required to advise the Secretary as to the ethical acceptability of such research (45 CFR 46.204(d)). Without congressional oversight, the failure since 1980 of successive Secretaries of Health and Human Services to appoint an EAB is likely to continue. Consequently, questions surrounding the interaction of sperm and egg—fundamental to an understanding of conception and contraception—remain largely uninvestigated.

In addition, research into the efficacy and risks of some infertility treatments such as IVF and gamete intrafallopian transfer are largely uninvestigated and lie outside the sphere of Federal funding and peer review. Finally, in an era of heightened concern about the ability of the United States to compete internationally, it is noteworthy that major developments in early embryo research are most likely to occur in nations such as Australia and the United Kingdom, where the research climate is more favorable.

Option 2: Expand Federal support for research in male infertility.

With the principal cause of male infertility being abnormal or too few sperm, due to unknown factors, efforts on prevention and treatment are largely guesswork. Some contend that studies of the reproductive health of men have been poorly designed and are too inadequate to draw any firm conclusions.

Congress could direct the Secretary of Health and Human Services to convene an interagency task force to report on the scope and adequacy of Federal research efforts into the reproductive health of men. Congress could direct the task force to identify a coordinator and an appropriate lead agency for a strengthened, government-wide effort to identify the causes of and treatments for male infertility.

Such an effort would probably require a 5- to 10-year sustained commitment of additional funds for research. The outcome of such a commitment would likely be positive identification of some risk factors for male infertility that are today unrecog-

nized. In addition, long-sought-after progress in development of male contraceptive methods is likely to accompany advances in understanding male infertility.

It is important to note that expanded Federal support for research in male infertility does not represent an alternative to continued research in female infertility. Both are required for progress in understanding infertility.

Option 3: Expand Federal support for research on the psychology of participants in assisted conception.

The positive and negative impacts of infertility and novel reproductive technologies on the behavior of individuals and on society as a whole have been little studied. Congress could exercise oversight to see that the research agencies that support the social, behavioral, and psychological sciences place research on the psychology of participants in assisted reproduction high on their priority lists.

Option 4: Direct the Secretary of Health and Human Services to review, solely for scientific merit, research involving human sperm, eggs, and early embryos.

In some other nations, Governments and advisory bodies have declared that it is acceptable to do research with human sperm and eggs and with embryos of not more than 14 days of age. Congress could direct the Secretary of Health and Human Services to consider in routine fashion proposals to conduct such research (i.e., review them solely for scientific merit) and specifically exempt them from the regulatory requirement for review by an EAB.

Option 5: Mandate the appointment of an Ethics Advisory Board within the Department of Health and Human Services.

In 1974, the Department of Health, Education, and Welfare established an EAB to review research proposals that raise sensitive ethical questions. Since 1980, no Board has been appointed. Areas of infertility research that raise sensitive ethical questions, such as research into the events surrounding human fertilization, are directly affected by the absence of an EAB. Such research cannot be funded by the National Institutes of Health without review by an Ethics Advisory Board. Congressional oversight may be sufficient—or legislation may be required—to resolve the question of the failure of the Department of Health and Human Services to abide by its own regulation requiring appointment of an EAB.

Option 6: Direct the Secretary of Health and Human Services to implement (and update as needed) the 1979 recommendations of the Ethics Advisory Board.

The 1979 report of the EAB of the Department of Health, Education, and Welfare found that research involving human IVF is ethically acceptable. It concluded that "a broad prohibition of research involving human IVF is neither justified nor wise."

With regard to Federal support of research involving human IVF, the Board concluded that Federal involvement is ethically acceptable and might help to resolve questions of risk and avoid abuse by encouraging well-designed research by qualified scientists. Further, Federal involvement might help shape the use of the procedures through regulation and by example. The conditions, for example, under which researchers could manipulate embryos that are not transferred following IVF would almost certainly be defined in any federally supported research protocol.

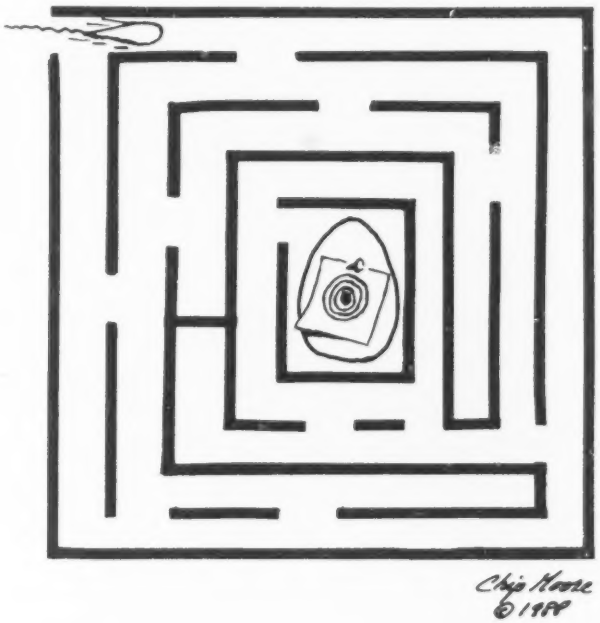
Congress could mandate that the Secretary of Health and Human Services incorporate the 1979 conclusions and recommendations of the EAB into departmental practice, updating them as needed. This action, along with appointment of an EAB, would likely end the de facto moratorium on Federal support for research involving human IVF. Increased research into the efficacy and risks of IVF and allied procedures would provide a base of knowledge to protect infertile couples who are today readily availing themselves of such procedures.

Option 7: Direct the congressional Biomedical Ethics Board to develop guidelines for federally funded research with human sperm, eggs, and embryos.

Unlike the United Kingdom, Australia, and a number of other nations, the U.S. Government

has not formally evaluated the prevailing ethical standards surrounding reproductive technologies. The congressional Biomedical Ethics Board was established to report on the ethical issues arising from the delivery of health care and biomedical research, including the protection of human subjects of such research.

Congress could direct this Board to report on the ethical implications of public policies related to artificial insemination, egg donation, cryopreservation of gametes and embryos, IVF, surrogate motherhood, and other biological and social solutions to infertility. Such a report would establish ethical guideposts for Federal agencies supporting research in these areas. In addition, it would serve the valuable historical purpose of standing as a landmark of the limits on ethically acceptable research and clinical care as American society enters the 1990s.



NOTE: Copies of the report "Infertility: Medical and Social Choices" can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325, GPO stock No. 052-003-01091-7; $16.00.

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